In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 04-405V
(To be published)

* *		
MARCIE and ALAN BROOK, parents of N.B., a minor,	*	
Petitioners,	*	Filed: May 14, 2015
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES	*	Vaccine Act Entitlement; Causation-in-fact; MMR-Varivax/ Autism Spectrum Disorder.
Respondent.	*	
* *		

Clifford Shoemaker, Shoemaker, Gentry & Knickelbein, Vienna, VA, for Petitioners.
Linda Renzi, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION

HASTINGS, *Special Master*.

This is an action in which Petitioners, Marcie and Alan Brook, seek an award under the National Vaccine Injury Compensation Program (hereinafter "the Program"[1]), on account of their son N.B.'s autism spectrum disorder ("ASD"), which they assert to have been caused or aggravated by one of the vaccinations (MMR, varicella, and pneumococcal) administered to their son on June 13, 2001. For the reasons set forth below, I conclude that Petitioners are not entitled to an award.

I

THE APPLICABLE STATUTORY SCHEME

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered

[1] The applicable statutory provisions defining the Program are found at 42 U.S.C. § 300aa-10 *et seq.* (2006 ed.). Hereinafter, for ease of citation, all "§" references will be to 42 U.S.C. (2006 ed.).

a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a *causal link* between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300 aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

In other cases, however, the vaccine recipient may have suffered an injury *not* of the type covered in the Vaccine Injury Table. In such instances, an alternative means exists to demonstrate entitlement to a Program award. That is, the petitioner may gain an award by showing that the recipient's injury was "caused-in-fact" by the vaccination in question. § 300aa-13(a)(1)(B); § 300aa-11(c)(1)(C)(ii). In such a situation, of course, the presumptions available under the Vaccine Injury Table are inoperative. The burden is on the petitioner to introduce evidence demonstrating that the vaccination actually caused the injury in question. *Althen v. HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Hines v. HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991). The showing of "causation-in-fact" must satisfy the "preponderance of the evidence" standard, the same standard ordinarily used in tort litigation. § 300aa-13(a)(1)(A); *see also Althen*, 418 F.3d at 1279; *Hines*, 940 F.2d at 1525. Under that standard, the petitioner must show that it is "more probable than not" that the vaccination was the cause of the injury. *Althen*, 418 F.3d at 1279. The petitioner need not show that the vaccination was the sole cause or even the predominant cause of the injury or condition, but must demonstrate that the vaccination was at least a "substantial factor" in causing the condition, and was a "but for" cause. *Shyface v. HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Thus, the petitioner must supply "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury;" the logical sequence must be supported by "reputable medical or scientific explanation, *i.e.*, evidence in the form of scientific studies or expert medical testimony." *Althen*, 418 F.3d at 1278; *Grant v. HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992).

The *Althen* court also provided additional discussion of the "causation-in-fact" standard, as follows:

> Concisely stated, Althen's burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury. If Althen satisfies this burden, she is "entitled to recover unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine."

Althen, 418 F.3d at 1278 (citations omitted). The *Althen* court noted that a petitioner need not necessarily supply evidence from *medical literature* supporting petitioner's causation contention,

so long as the petitioner supplies the *medical opinion* of an expert. (*Id*. at 1279-80.) The court also indicated that, in finding causation, a Program fact-finder may rely upon "circumstantial evidence," which the court found to be consistent with the "system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." (*Id*. at 1280.)

Since *Althen*, the Federal Circuit has addressed the causation-in-fact standard in several additional rulings, which have affirmed the applicability of the *Althen* test, and afforded further instruction for resolving causation-in-fact issues. In *Capizzano v. HHS*, 440 F.3d 1317, 1326 (Fed. Cir. 2006), the court cautioned Program fact-finders against narrowly construing the second element of the *Althen* test, confirming that circumstantial evidence and medical opinion, sometimes in the form of notations of treating physicians in the vaccinee's medical records, may in a particular case be sufficient to satisfy that second element of the *Althen* test. Both *Pafford v. HHS*, 451 F.3d 1352, 1355 (Fed. Cir. 2006), and *Walther v. HHS*, 485 F.3d 1146, 1150 (Fed. Cir. 2007), discussed the issue of which party bears the burden of ruling out potential non-vaccine causes. *DeBazan v. HHS*, 539 F.3d 1347 (Fed. Cir. 2008), concerned an issue of what evidence the special master may consider in deciding the initial question of whether the petitioner has met her causation burden. The issue of the temporal relationship between vaccination and the onset of an alleged injury was further discussed in *Locane v. HHS*, 685 F.3d 1375 (Fed. Cir. 2012), and *W.C. v. HHS*, 704 F.3d 1352 (Fed. Cir. 2013). *Moberly v. HHS*, 592 F.3d 1315 (Fed. Cir. 2010), concluded that the "preponderance of the evidence" standard that applies to Vaccine Act cases is the same as the standard used in traditional tort cases, so that *conclusive* proof involving medical literature or epidemiology is *not* needed, but demonstration of causation must be more than "plausible" or "possible." Both *Andreu v. HHS*, 569 F.3d 1367 (Fed. Cir. 2009), and *Porter v. HHS*, 663 F.3d 1242 (Fed. Cir. 2011), considered when a determination concerning an expert's credibility may reasonably affect the outcome of a causation inquiry. *Broekelschen v. HHS*, 618 F.3d 1339 (Fed. Cir. 2010), found that it was appropriate for a special master to determine the reliability of a diagnosis before analyzing the likelihood of vaccine causation. *Lombardi v. HHS*, 656 F.3d 1343 (Fed. Cir. 2011), and *Hibbard v. HHS*, 698 F.3d 1355 (Fed. Cir. 2012), both again explored the importance of assessing the accuracy of the diagnosis that supports a claimant's theory of causation. *Doe 11* v. HHS, 601 F.3d 1349 (Fed. Cir. 2010) and *Deribeaux v. HHS*, 717 F.3d 1363 (Fed. Cir. 2013), both discuss the burden of proof necessary to establish that a "factor unrelated" to a vaccine may have caused the alleged injury.

Another important aspect of the causation-in-fact case law under the Program concerns the factors that a special master should consider in evaluating the reliability of expert testimony and other scientific evidence relating to causation issues. In *Daubert v. Merrell Down Pharmaceuticals, Inc*., 509 U.S. 579 (1993), the Supreme Court listed certain factors that federal trial courts should utilize in evaluating proposed expert testimony concerning scientific issues. In *Terran v. HHS*, 195 F.3d 1302, 1316 (Fed. Cir. 1999), the Federal Circuit ruled that it is appropriate for special masters to utilize *Daubert*'s factors as a framework for evaluating the reliability of causation-in-fact theories presented in Program cases.

II

THE OMNIBUS AUTISM PROCEEDING ("OAP")

This case is one of more than 5,400 cases filed under the Program in which petitioners alleged that conditions known as "autism" or "autism spectrum disorders" ("ASD") were caused by one or more vaccinations. A special proceeding known as the Omnibus Autism Proceeding ("OAP") was developed to manage these cases within the Office of Special Masters ("OSM"). A detailed history of the controversy regarding vaccines and autism, along with a history of the development of the OAP, was set forth in the six entitlement decisions issued by three special masters as "test cases" for two theories of causation litigated in the OAP (see cases cited below), and will only be summarized here.

A group called the Petitioners' Steering Committee ("PSC") was formed in 2002 by the many attorneys who represented Vaccine Act petitioners who raised autism-related claims. About 180 attorneys participated in the PSC. Their responsibility was to develop any available evidence indicating that vaccines could contribute to causing autism, and eventually present that evidence in a series of "test cases," exploring the issue of whether vaccines could cause autism, and, if so, in what circumstances. Ultimately, the PSC selected groups of attorneys to present evidence in two different sets of "test cases" during many weeks of trial in 2007 and 2008. In the six test cases, the PSC presented two separate theories concerning the causation of ASDs. The first theory alleged that the *measles* portion of the measles, mumps, rubella ("MMR") vaccine could cause ASDs. That theory was presented in three separate Program test cases during several weeks of trial in 2007. The second theory alleged that the mercury contained in *thimerosal-containing vaccines* could directly affect an infant's brain, thereby substantially contributing to the causation of ASD. That theory was presented in three additional test cases during several weeks of trial in 2008.

Decisions in each of the three test cases pertaining to the PSC's *first* theory rejected the petitioners' causation theories. *Cedillo v. HHS*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009) *aff'd*, 89 Fed. Cl. 158 (2009), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010); *Hazlehurst v. HHS*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd* 88 Fed. Cl. 473 (2009), *aff'd*, 604 F.3d 1343 (Fed. Cir. 2010); *Snyder v. HHS*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009).[2] Decisions in each of the three "test cases" pertaining to the PSC's *second* theory also rejected the petitioners' causation theories, and the petitioners in each of those three cases chose not to appeal. *Dwyer v. HHS*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *King v. HHS*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar 12, 2010); *Mead v. HHS*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

The "test case" decisions were comprehensive, analyzing in detail all of the evidence presented on both sides. The three test case decisions concerning the PSC's *first* theory (concerning the MMR vaccine) totaled more than 600 pages of detailed analysis, and were solidly affirmed in many more pages of analysis in three different rulings by three different judges of the United States Court of Federal Claims, and in two rulings by two separate panels of the United States Court of Appeals for the Federal Circuit. The three special master decisions

[2] The petitioners in *Snyder* did not appeal the ruling to the U.S. Court of Appeals for the Federal Circuit.

concerning the PSC's *second* theory (concerning vaccinations containing the preservative "thimerosal") were similarly comprehensive.

All told, the 11 lengthy written rulings by the special masters, the judges of the U.S. Court of Federal Claims, and the panels of the U.S. Court of Appeals for the Federal Circuit *unanimously rejected* the petitioners' claims, finding no persuasive evidence that either the MMR vaccine or thimerosal-containing vaccines could contribute in any way to the causation of autism.

Thus, the proceedings in the six "test cases" concluded in 2010. Thereafter, the Petitioners in this case, and the petitioners in other cases within the OAP, were instructed to decide how to proceed with their own claims. The vast majority of those autism petitioners elected either to withdraw their claims or, more commonly, to request that the special master presiding over their case decide their case on the written record, uniformly resulting in a decision rejecting the petitioner's claim for lack of support. However, a small minority of the autism petitioners have elected to continue to pursue their cases, seeking other causation theories and/or other expert witnesses. A few such cases have gone to trial before a special master, and in the cases of this type decided thus far, all have resulted in rejection of petitioners' claims that vaccines played a role in causing their child's autism. *See, e.g.*, *Blake v. HHS*, No. 03-31V, 2014 WL 2769979 (Fed. Cl. Spec. Mstr. Vowell May 21, 2014) (autism not caused by MMR vaccination); *Henderson v. HHS*, No. 09-616V, 2012 WL 5194060 (Fed. Cl. Spec. Mstr. Vowell Sept. 28, 2012) (autism not caused by pneumococcal vaccination); *Franklin v. HHS*, No. 99-855V, 2013 WL 3755954 (Fed. Cl. Spec. Mstr. Hastings May 16, 2013) (MMR and other vaccines found not to contribute to autism); *Coombs v. HHS*, No. 08-818V, 2014 WL 1677584 (Fed. Cl. Spec. Mstr. Hastings Apr. 8, 2014) (autism not caused by MMR or Varivax vaccines); *Long v. HHS*, No. 08-792V, 2015 WL 1011740 (Fed. Cl. Spec. Mstr. Hastings Feb. 9, 2015) (autism not caused by influenza vaccine). In addition, some causation autism claims have been rejected without trial, at times over the petitioner's objection, in light of the failure of the petitioner to file plausible proof of vaccine-causation. *See, e.g.*, *Waddell v. HHS*, No. 10-316V, 2012 WL 4829291 (Fed. Cl. Spec. Mstr. Campbell-Smith Sept. 19, 2012) (autism not caused by MMR vaccination); *Geppert v. HHS*, No. 00-286V, 2013 WL 2500852 (Fed. Cl. Spec. Mstr. Vowell Sept. 6, 2012); *Fesanco v. HHS*, No. 02-1770, 2010 WL 4955721 (Fed. Cl. Spec. Mstr. Hastings Nov. 9, 2010); *Fresco v. HHS*, No. 06-469V, 2013 WL 364723 (Fed. Cl. Spec. Mstr. Vowell Jan. 7, 2013); *Pietrucha v. HHS*, No. 00-269V, 2014 WL 4538058 (Fed. Cl. Spec. Mstr. Hastings Aug. 22, 2014). Judges of this court have affirmed the practice of dismissal without trial in such a case. *E.g.*, *Fesanco v. HHS*, 99 Fed. Cl. 28 (May 16, 2011) (Judge Braden).

In none of the rulings since the test cases has a special master or judge found any merit in an allegation that any vaccine can contribute to causing autism.

III

PROCEDURAL HISTORY OF THIS CASE

Petitioners filed a Short-Form Autism Petition for Compensation on behalf of their son N.B. on March 12, 2004. (ECF No. 1.) On March 19, 2004, this case was stayed indefinitely pending completion of the general inquiry under the Omnibus Autism Proceeding regarding the

possible causal relationship between certain vaccines and autistic spectrum disorders. (See Section II of this Decision above.)

On September 13, 2007, Petitioners filed medical records marked as Exhibits 1-34. (ECF No. 13.)

Following the resolution of the autism "test cases," Petitioners filed an amended petition on July 14, 2011, alleging that N.B. "developed mercury poisoning and toxic/static encephalopathy" as a result of his MMR and Varicella vaccinations administered on June 13, 2001, as well as his Hib vaccination of October 8, 2001.[3] (ECF No. 15.) On June 6, 2013, Petitioners filed narrative statements by N.B.'s parents marked as Exhibits 35 and 36, along with medical literature marked as Exhibits 37-42, an expert medical report by Joseph Bellanti, M.D. marked as Exhibit 43, and a CV of Dr. Bellanti marked as Exhibit 44.

Respondent filed a "Rule 4 report" on November 8, 2013. (ECF No. 33.) Respondent's report took the position that compensation is not appropriate under the Vaccine Act. At that same time, Respondent also filed an expert medical report by Christine McCusker, MD, marked as Exhibit A, accompanied by a CV marked as Exhibit B, and supporting medical literature marked as Exhibits C-L. (ECF Nos. 34, 35.)

Both Respondent's "Rule 4 report" and expert report indicated that no medical records from N.B.'s primary care physician were filed for the period 2000 through 2002. (ECF No. 33, p. 2; Ex. A, p. 1.) Petitioners filed these records as Exhibit 45 on December 16, 2013.[4] (ECF No. 37.)

Petitioners submitted a pre-hearing brief on January 21, 2014 (ECF No. 40), and Respondent filed a pre-hearing brief on January 22, 2014 (ECF No. 41). A hearing was conducted at the Office of Special Masters on April 25, 2014 (*see* Transcript of Proceedings ("Tr."), ECF No. 47.) Dr. and Mrs. Brook testified by telephone, while both Dr. Bellanti and Dr. McCusker testified in person. (*Id*.)

On August 28, 2014, Petitioners filed a post-hearing brief. (ECF No. 52.) Respondent filed an opposing brief on December 5, 2014, (ECF No. 56), and Petitioners filed a reply brief on January 18, 2015 (ECF No. 59).

[3] However, Petitioners' expert Dr. Bellanti at times was unclear as to *which* of the vaccines of June 13, 2001, he thought were injurious to N.B. (See fn. 13 below.) Further, Petitioners apparently *abandoned* the allegation that the vaccination of *October 8*, 2001, injured N.B., failing to pursue that allegation in Dr. Bellanti's expert report or hearing testimony.

[4] Both experts later confirmed at the hearing in this case that they reviewed these records subsequent to writing their reports but before testifying in this case. (Tr. 71-73, 105.)

IV

FACTUAL HISTORY

A. Facts reflected in the medical records

N.B. was born on June 12, 2000, after approximately 37 weeks of gestation. (Ex. 33, p. 14.) His birth was complicated; he was "limp/blue" at delivery, requiring resuscitation. (*Id*., pp. 16, 22.) N.B. remained in the newborn special care unit for three days. (*Id*., p. 18.)

No problems were reported at N.B.'s two, four, and six month well-baby exams with his primary care physician, Dr. Lazaroff. (Ex. 45, pp. 19, 23, 25.) At these visits N.B. received routine vaccinations. (*Id*.)

On March 1, 2001, N.B.'s records note that he was not sitting alone at that time, had increased tone, and that he arched when sitting. (*Id*., p. 26.) He was referred to a neurologist, Dr. Denis Altman, who indicated that N.B. exhibited mild hypertonia with no evidence of spastic quadriplegia. (Ex. 7, p. 20.) Dr. Altman recommended physical therapy. (*Id*.) Later, on April 11, 2001, N.B. was seen, and it was noted that he had gross motor delay and was hypertonic. (Ex. 45, p. 27.) Dr. Lazaroff noted that N.B. was "not crawling – not getting to sitting." (*Id.*) Dr. Lazaroff also noted feeding issues, and indicated that occupational therapy would be considered if the problems persisted. (*Id*.)

By June 6, 2001, Dr. Altman reported that N.B. was making "excellent gains" and that he was "sitting, crawling, beginning to stand," with "good social skills." (Ex. 7, p. 19.) Dr. Altman's impression for that visit was "normal." (*Id*.) Despite this progress, however, N.B. remained at the 27th percentile for gross motor skills. (Ex. 24, p. 53.) Dr. Altman recommended continued physical therapy, and that N.B.'s language be monitored. (Ex. 7, p. 19.)

Shortly thereafter, on June 13, 2001, N.B. had his one-year well visit, at which time he received "MMR" (measles, mumps, rubella), Varivax (varicella), and Prevnar (pneumococcal) vaccinations. (Ex. 45, p. 29.) Ten days later, on June 23, 2001, N.B. was seen again, for a rash thought to be secondary to his Varivax vaccination.[5] (*Id*., p. 30.) The record of this visit mentions the fact of the vaccination 10 days previously, but indicates that the parent who brought N.B. for the check-up *specifically denied* that N.B. was suffering besides the rash, any symptoms of illness, including fever. (*Id*.)

At a visit on October 8, 2001, N.B. received a further dose of HIB (hemophilus influenza type B) vaccine. (Ex. 45, p. 31.) He was seen again on October 25 with fever and rash, which symptoms were recorded as the potential result of a Coxsackie viral infection. (*Id*., p. 32).

At his visit of November 7, 2001, with Dr. Altman, it was noted that N.B. pulled to stand, but was not yet walking, used 3-5 words, babbled, played repetitively, and did not yet have fantasy play. (Ex. 7, p. 18.) Dr. Altman's diagnostic impression was "static encephalopathy with global delay." (*Id*.) Dr. Altman also noted that N.B. was "ok" socially, but needed to be monitored for a possible autism spectrum disorder. (*Id.*) Speech and language therapy, along

[5] In fact, both experts in this case indicated that both the MMR and varicella vaccines can produce a rash at about ten days, and that the MMR vaccine could also have been the cause of the rash. (Tr. 58, 110.)

with physical and occupational therapies, were recommended. (*Id*.) A physical therapy reevaluation on December 19, 2001, indicated that, at 18 months of age, N.B. had the fine motor skills of a 15-month-old. He had normal muscle tone, but decreased trunk strength and safety awareness. (Ex. 18, pp. 10-11, 40-42.)

N.B. underwent speech and language evaluation on January 22, 2002. (Ex. 24, pp. 90-92.) His mother gave a history that indicated that he babbled and cooed at 4 months, used his first word at 10 months, and had an "extremely limited vocabulary." (*Id*., p. 90.) N.B. was diagnosed as having delay in speech articulation, language comprehension, and language expression. (*Id*.) Specifically, at 19 months of age N.B.'s language comprehension and play skills were determined to be at the 12-15 month level, while his expression and interaction/attachment were at the 9-12 month level. (*Id*., pp. 91-92.)

On March 19, 2002, Dr. Altman indicated that N.B. was making "definite but slow progress," describing "definite" language delay, and maintaining his diagnostic impression of "static encephalopathy with global delay." (Ex. 7, p. 17.) Dr. Altman observed that N.B. was making some sounds, but without intent, and that he communicated by grunts. (*Id*.) It was recommended that N.B. continue his services, and noted in particular that he needed "aggressive" speech and language therapy. (*Id*.) Although autism is not mentioned in Dr. Altman's March 19 record, an April 2002 progress note by N.B.'s occupational therapist indicates that the family had been speaking during this time period with therapy staff about a possible autism diagnosis suggested by N.B.'s neurologist. (Ex. 18, p. 28.)

In July of 2002, at 25 months of age, N.B. was evaluated in an inclusive classroom setting at the Good Shepherd School for Children. (Ex. 12, pp. 147-48.) He was found to have the cognitive skill level of a 9-11 month old, but received no scoring in many areas, because he was unable to comply with requests. (*Id*., p. 148.) He did not respond to his name, and cried intermittently, particularly when peers came near. (*Id*., p. 147.) N.B. was "very overwhelmed" by the school environment and was hypersensitive to his environment the majority of the time. (*Id*., p. 199.) He could be calmed with "vestibular input, deep pressure, and rhythmic music." (*Id*.) At around this time, N.B.'s speech therapist noted that "[N.B.] has demonstrated difficulty in relating to people," and that he appeared aloof and demonstrated only minimal eye contact. (Ex. 7, p. 41.) It was also noted that N.B.'s play was limited and that he had a "very limited repertoire of play skills." (*Id*., p. 42.)

N.B. was seen again by Dr. Altman on August 15, 2002. (Ex. 7, p. 16.) At this time, Dr. Altman noted that at age 26 months, N.B. had very little communication, poor eye contact, and echolalia. (*Id*.) For this visit, Dr. Altman's diagnostic impression reads "Autism Spectrum Disorder." (*Id*.)

In August of 2002, N.B. switched speech therapists and was evaluated on August 28 by Therapy Relief Incorporated. (Ex. 27, pp. 25-26.) At this evaluation, N.B. presented with a "severe receptive and expressive language disorder" and "possible severe developmental apraxia of speech."[6] (*Id.*, p. 26.) N.B.'s language scores were two standard deviations below the mean,

[6] Apraxia of speech was later confirmed by a speech pathologist who diagnosed N.B. as falling in the "severe" range. (Ex. 5, pp. 3-5.)

reflecting a 50% delay with language skills for his age. (*Id*., p. 25.) He had difficulty following instructions and used only about 10 words. His mother reported that he had lost words he previously used, but also reported that "all developmental milestones with [N.B.] have followed the normal progression; however, he has been very late." (*Id*.)

N.B. was evaluated at the Judevine Center for Autism in October of 2002, scoring 26 on the Childhood Autism Rating Scale based on parental reporting, which fell within the non-autistic range of the scale. (Ex. 13, pp. 18-19.) Based on the assessor's interaction, however, N.B. scored 39, which fell in the "severely autistic" range. (*Id.*)

N.B.'s records indicated that overall he continued making progress in his therapies throughout 2003 and 2004. For example, Dr. Altman noted in August of 2004 that "he's made marked improvement in all aspects of his neurological functioning over the last 18 months." (Ex. 7, p. 10.) Dr. Altman noted in particular that N.B. was using more language, beginning to understand more commands, and that his social interaction had improved to the point that he could attend pre-school with an aide. (*Id*.)

At that time, N.B. was being evaluated for "the possibility of a biological or metabolic disorder" to explain his syndrome. (*Id*.) Based on an unspecified biological work-up, Dr. Altman indicated that his "overall feeling is that [N.B.] does not have a degenerative or underlying identifiable metabolic or biochemical disease." (*Id*.) N.B.'s progress was to be monitored before any more comprehensive evaluation for mitochondrial disorder would be conducted. (*Id*., pp. 10-11.) Later blood tests, in November of 2004, indicated that N.B. had elevated levels of lactic acid and pyruvic acid. (Ex. 7, p. 67.)

N.B.'s therapies continued thereafter and N.B. continued to make progress. (*See, e.g*., Ex. 32, pp. 13-16 (noting N.B.'s current level of function as of May 25, 2005).) In June of 2005, N.B. reached five years of age, and was considered for enrollment in kindergarten. (Ex. 20, pp. 262-65.) In a Special School District Resolution Conference Report, it was recommended that N.B. move from in-home education services to a school age program at the Bellerive Elementary School, a center for applied behavioral analysis with special programs for autistic students. (*Id*., pp. 263-64.)

B. Additional facts reported by N.B.'s parents

In addition to the above, both of N.B.'s parents provided written narratives and testimony further describing N.B.'s clinical course. (Ex. 35; Ex. 36; Tr. 4-50.) Overall, their recollection of events mostly agreed with what is reflected in the medical records. However, concerning the key facts surrounding N.B.'s alleged *immediate* reaction to his vaccinations of June 13, 2001, and the onset of his symptoms of ASD, the parents presented certain facts which are at *variance* with N.B.'s contemporaneous medical records.

In his narrative, N.B.'s father, Dr. Brook, stated that after N.B. received his vaccinations of June 13, 2001, N.B. "experienced high fever to 104 for 2 days. He screamed loudly for 24 hours." (Ex. 35, p. 1.) At the hearing, Dr. Brook further elaborated, indicating that "I remember him having fever and just being extremely irritable and crying. I think he slept very poorly those next two days, and we just couldn't seem to calm him down." (Tr. 12-13.) Dr. Brook indicated

that "that kind of was the beginning of what became a behavior that we saw a lot of over those next several months * * *. And after those vaccines, his whole personality seemed to change." (Tr. 13.) Dr. Brook testified that N.B. had had reactions to prior vaccinations, but that this was "more severe" than before, and that it was "particularly severe right after the vaccination." (*Id*.)

In addition, N.B.'s mother, stated in her narrative that after the vaccinations of June 13, 2001, N.B. seemed "out of sorts for days," that he "cried quite frequently," "ran a fever," and "had chronic diarrhea and was inconsolable." (Ex. 36, p.1.) At the hearing, she testified that following those vaccinations N.B. "kind of seemed out of it for days," and that "something was wrong." (Tr. 41.) She indicated that N.B. cried, was inconsolable, and ran a high fever. (*Id*.) She testified that she couldn't remember when exactly this reaction started, but she indicated that she believed it occurred prior to her return visit to Dr. Lazaroff on June 23, 2001, concerning N.B.'s subsequent rash. (*Id*.) She also testified that N.B. was out of character, "zoned out," experienced sensitivity to light and sound, and had unusual behaviors such as "flapping his hands" and "high-pitched vocalizations." (Tr. 42.)

V

SUMMARY OF EXPERT WITNESSES' QUALIFICATIONS AND OPINIONS

In this case, Petitioners and Respondent each presented an expert report and testimony from a medical expert. At this point, I will briefly summarize both the qualifications and the opinions of these expert witnesses.

A. Petitioners' expert, Dr. Joseph Bellanti

1. Qualifications

Joseph A. Bellanti, M.D., received his Doctor of Medicine (M.D.) from the University of Buffalo School of Medicine in 1958. (Ex. 44, p. 3.) He completed residency training at Children's Hospital of Buffalo, New York, from 1959 to 1961. (*Id*.) He was a special NIH trainee in Immunology at the J. Hillis Miller Health Center in Gainesville, Florida, and a research virologist at the Walter Reed Army Institute of Research, before moving on to serve in a number of capacities with Georgetown University where he has served from 1963 to the present. (*Id*.)

Currently, Dr. Bellanti serves as director of the International Center for Interdisciplinary Studies of Immunology at Georgetown University where he is also a professor of pediatrics and of microbiology-immunology. (Ex. 44, p. 1.) Dr. Bellanti also serves at the Georgetown University Hospital, where he is the director of Immunology and Virology in the Department of Laboratory Medicine. (*Id*., p. 1.) He is also on the academic staff in pediatrics of Children's Hospital National Medical Center, as well as being a member of the department of pediatrics at both Arlington Hospital and INOVA Fairfax Hospital. (*Id*.)

Dr. Bellanti is licensed to practice medicine in New York, Maryland, Virginia, and the District of Columbia. He is board-certified in pediatrics, and is a Diplomate of both the National Board of Medical Examiners and the American Board of Allergy and Immunology. (Ex. 44, p. 4.) He is a fellow of the American Academy of Pediatrics, the American Academy of Allergy, the American College of Allergists, and the American Association for Clinical Immunology and

Allergy. (*Id*.) He has held numerous positions in scientific and professional societies, and is a past president of the American College of Allergy and Immunology and the Association of Medical Laboratory Immunologists. He has been on the editorial boards of seven different pediatric and allergy publications. (*Id*., pp. 5-6.)

Dr. Bellanti has also served on a number of committees, including the Growth and Development Committee of the National Institutes of Health and Human Development, the Allergy and Immunology Research Committee of the National Institute of Allergy and Infectious Diseases, and the American College of Allergy Board of Regents. (Ex. 44, p. 7.) He is a past member of the Board of Directors for the American Board of Medical Laboratory Immunology as well as the American College of Allergy Board of Regents. He is currently a member of the Institutional Review Board. (*Id*.)

Dr. Bellanti lists numerous awards and lectures on his curriculum vitae. He has published 234 articles as either lead or contributing author, and has written or contributed to 59 book chapters. (Ex. 44, pp. 12-26.)

2. Summary of Dr. Bellanti's opinion

Dr. Bellanti provided both an expert report (Ex. 43) and oral testimony at hearing (Tr. 52-102). His opinion was never very clearly explained, but as I understand it, the gist of his opinion can be summarized as follows. Dr. Bellanti opined that N.B. suffered an "encephalopathy" (brain injury) that resulted in a global developmental delay, causing symptoms consistent with ASD. (*E.g.*, Ex. 43, pp. 9, 10, 12; Tr. 56.) Dr. Bellanti argued that such encephalopathy was likely caused by vaccines that N.B. was given on June 13, 2001, which were MMR, varicella, and pneumococcal vaccines. (Ex. 43, pp. 10, 12; Tr. 56-57.) Further, as to *how* the vaccines caused the encephalopathy, his main theory seemed to be that the vaccines caused N.B.'s *own immune system* to mistakenly attack his brain--*i.e.*, an "autoimmune" theory. (Ex. 43, pp. 11-12; Tr. 57-62, 65-66.)

Initially, Dr. Bellanti in his report advanced four (and possibly more) separate theories to explain *how* N.B.'s vaccinations could cause such an autoimmune response. These were: "molecular mimicry," "polyclonal activation," "bystander effect," "adjuvant effect," "and such other theories as I have discussed in other reports." (*Id*., p. 11.) At the hearing in this case, however, Dr. Bellanti narrowed his opinion. He clarified that he believed molecular mimicry was not a likely explanation for N.B.'s condition, and that the likely mechanism was either polyclonal activation or bystander effect. (Tr. 98-99.)

Under a polyclonal activation theory, Dr. Bellanti argued, in a person "genetically predisposed," a vaccine can induce a "generalized stimulation of the immune system," which leads to "autoantibodies attacking host organs." (Ex. 43, p. 11.) He also stated that "[b]ystander activation is an antigen non-specific theoretical mechanism, where the vaccination can cause the tissue damage which leads to the release of self-antigens that are taken up by antigen presenting cells of the innate immune system." (*Id*.) Dr. Bellanti testified that he found it "difficult to say" which of these two mechanisms occurred in N.B.'s case, but stated that both theories are premised on the persistence of an "antigen" within N.B.'s body. (Tr. 98-99.)

B. Respondent's expert, Dr. Christine McCusker

1. Qualifications

Christine McCusker, M.D., MSc, FRCP, received her Master of Science (MSc) and her Medical Doctor (MD) degrees from McMaster University in Hamilton, Ontario, in 1988 and 1993 respectively. (Ex. A, p. 1.) From 1993 to 1999 she completed a residency training program in pediatrics and a clinical fellowship in allergy and immunology at McGill University in Montreal, Quebec. (*Id*., p. 2.) Currently she is an associate professor of allergy and immunology in the department of Pediatrics at the Montreal Children's Hospital and McGill University. (Ex. A, p. 3.) She is also a research director for Meakins-Christie Laboratories and a staff physician and director of the Clinical Immunology Laboratory at Montreal Children's Hospital. (*Id*., pp. 3-4.)

Additionally, Dr. McCusker serves on a number of committees, including the Hereditary Angioedema Society and Primary Immunodeficiency Network, the Canadian Immunodeficiency Patient Organization Scientific Advisory Committee, and the Examination Committee of the Royal College of Physicians and Surgeons of Canada. She is Chair of the Immunology Interest Section of the Canadian Society for Allergy and Clinical Immunology. (Ex. A, p. 13.)

As well as being licensed by the Medical Council of Canada, she is board-certified by the American Board of Pediatrics. She is a Fellow of the Royal College of Physicians and Surgeons of Canada, recognized in pediatrics as well as allergy and immunology. She is licensed by the College des Medecins du Quebec. (Ex. A, pp. 2-3.) Dr. McCusker is also a member of the Canadian Medical Protective Association, the Federation of Medical Specialists of Quebec, the Quebec Allergy and Immunology Association, and the Clinical Immunology Society. (*Id*., p. 14.)

In addition to her clinical and teaching duties, Dr. McCusker is an active researcher, listing numerous research grants on her curriculum vitae as well as three pending patent applications. (Ex. A, pp. 17-19.) Dr. McCusker has published 25 articles and one book chapter on topics relating to allergy and immunology. (*Id*., pp. 19-22.)

2. Summary of Dr. McCusker's opinion

Although Dr. McCusker did not disagree with Dr. Bellanti's opinion that N.B. likely experienced a static encephalopathy (Tr. 124-25), she disagreed with the view that N.B.'s condition is in any way related to any of his vaccinations. (Tr. 105; Ex A, p. 8.) Dr. McCusker noted that N.B.'s developmental problems began *prior* to the vaccinations of June 13, 2001. She also noted that there is no evidence in N.B.'s case of CNS (central nervous system) inflammation, autoantibody formation, or CNS lesions associated with autoimmune encephalopathy, and that N.B. had a normal MRI--all of which contradict Dr. Bellanti's theory that N.B.'s symptoms were caused by an autoimmune response. (Ex. A, p. 8.) She also noted that there is no evidence of "persistent viral infection or chronic immune activation" to support Dr. Bellanti's "bystander effect" theory or his "polyclonal activation" theory (Ex. A, p. 6; Tr. 119-122.)

VI

SUMMARY OF MY DECISION

In this case, N.B.'s treating neurologist, Dr. Altman, initially diagnosed N.B. as having a "static encephalopathy with global delay." He later included ASD in his diagnostic impression. Neither expert witness in this case disputes the diagnoses made by Dr. Altman. The two experts differ greatly, however, in their interpretation of those diagnoses, their significance, and ultimately, their cause. After reviewing the record of this case, I have found Dr. Bellanti's view of the case to be quite unpersuasive,[7] while Dr. McCusker's opinion was far more persuasive. There are several reasons for this conclusion.

First and foremost, Dr. Bellanti based his causation opinion on two *faulty* factual assumptions, namely that after his vaccinations of June 13, 2001, N.B. experienced (1) an immediate severe vaccine reaction, and (2) a prompt post-vaccine developmental *regression*. For the reasons described below, I have determined that these factual assumptions are, much more likely than not, *incorrect*. (*See* Section VII below.) Dr. Bellanti's alternate theory regarding a possible autistic regression resulting from fever was likewise unsupported by the record of this case, in that it was conditional upon N.B. suffering a mitochondrial dysfunction. There is no substantial evidence of mitochondrial dysfunction in the record, and in any event, Dr. Bellanti did not ever actually opine that N.B. *did have* such dysfunction. (*See* Section IX, below.)

In addition, there are a number of other deficiencies in Dr. Bellanti's opinion. He did not substantiate his claim that autoimmune encephalopathy could result in symptoms consistent with ASD, and he acknowledged that no test results were available to substantiate his claim that N.B. experienced a vaccine-related encephalopathy. (Section VIII(A), below.) Moreover, his opinion was tentative and uncertain overall. (Section VIII(B), below.) And finally, Dr. Bellanti's opinion was refuted by a number of points raised by Dr. McCusker. (Section VIII(C), below.)

VII

DR. BELLANTI'S CAUSATION OPINION IS BASED ON FLAWED FACTUAL ASSUMPTIONS

Petitioners' expert, Dr. Bellanti, argued that N.B. suffered an encephalopathy caused by N.B.'s vaccinations of June 13, 2001. The most obvious deficiency in this presentation is that Dr. Bellanti's causation opinion is premised on assumptions that run *contrary* to the clinical history presented by the medical records.

Specifically, Dr. Bellanti opined in his expert report as follows: "it is clear that the live vaccines that [N.B.] received on June 13, 2001, * * * caused a significant change in his condition. He clearly had a severe immediate reaction to these vaccines (the fever and inconsolable crying), and the rash that appeared 10 days after the vaccination would be

[7] Petitioners have the burden of demonstrating the facts necessary for entitlement to an award by a "preponderance of the evidence." § 300aa-12(a)(1)(A). Under that standard, the existence of a fact must be shown to be "more probable than its nonexistence." *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring).

consistent with an adverse reaction to the vaccines. N.B.'s rather sudden regression after these vaccines makes it highly likely that he suffered a static encephalopathy (or significant aggravation of a preexisting static encephalopathy) as a result of these vaccinations that then led to his developmental delays and symptoms diagnosed as autism." (Ex. 43, p. 10.)

During the hearing in this case, Dr. Bellanti acknowledged that there are no clinical test results available to support his causation theory, but stressed that he believed that the combination of N.B.'s high fever and crying immediately after the vaccination, along with his subsequent developmental deterioration, suggest that his vaccinations contributed to his clinical condition. (Tr. 64.) Although Dr. Bellanti testified that his opinion was based "collectively" on all of the information in N.B.'s clinical history (Tr. 82-83), he repeatedly cited N.B.'s alleged immediate reaction to the vaccine and his alleged subsequent developmental regression as being key clinical indicators showing a logical "cause and effect" sequence supporting his opinion (Tr. 55-56, 58-59, 64, 82-83).

Thus, Dr. Bellanti's primary causal theory is clearly predicated on two factual assumptions: that N.B. experienced a *severe immediate reaction* to his June 13 vaccinations, and that he *soon thereafter* experienced a developmental *regression*. These assumptions, however, are *not* supported by the factual record of his case.

A. The medical records contradict the assumption that N.B. suffered a severe immediate reaction to his vaccination.

Dr. Bellanti admitted that there is no support in the *medical records* for his assumption that N.B. experienced a severe *immediate* reaction to his vaccinations. Instead, Dr. Bellanti relied upon statements and testimony from *N.B.'s parents* that N.B. experienced a fever of 104° for two days, plus loud screaming and uncontrollable crying, immediately after his vaccinations. (Ex. 43, pp. 2, 10; Tr. 58, 79.) Dr. Bellanti acknowledged that "the only thing that was mentioned [in N.B.'s medical records] was the reaction [a rash only] at ten days on the 23rd" (Tr. 79), but he relied upon the testimony of Dr. Brook, N.B.'s father. Dr. Bellanti stated that "you know, this history of being out of sorts, the father's history of 104° for two days was what I was basing my opinion on. I didn't see that documented in the medical records." (Tr. 80.) Thus, Dr. Bellanti testified that rather than relying on the medical records, "my opinion is based to quite a degree on Dr. Brook's [N.B.'s father's] testimony." (Tr. 79.)

In this case, however, I do *not* find that Dr. and Mrs. Brook's testimony establishes that it is more likely than not that N.B. experienced high fever, inconsolable crying, or any other symptoms of a severe vaccine reaction in June of 2001. Rather, I find that the medical records *contradict* Dr. Bellanti's assumption.

Medical records "warrant consideration as trustworthy evidence." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed.Cir.1993). Accordingly, where subsequent testimony conflicts with contemporaneous medical records, special masters usually accord more weight to the medical records. *See, e.g., Reusser v. Sec'y of Health & Human Servs.,* 28 Fed. Cl. 516, 523 (Fed. Cl. 1993) ("[W]ritten documentation recorded by a disinterested person at or soon after the event at issue is generally more reliable than the recollection of a party to a lawsuit many years later.").

To be sure, "it must [also] be recognized that the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance. Since medical records typically record only a fraction of all that occurs, the fact that reference to an event is omitted from the medical records may not be very significant." (*Murphy v. HHS*, 23 Cl. Ct. 726, 733 (Fed. Cl. 1991) (*aff'd* 968 F.2d 1226 (Fed. Cir. 1992)). However, in balancing these considerations, special masters in this Program have traditionally declined to credit later testimony over contemporaneous records. (*See, e.g., Stevens v. HHS*, 90-221V, 1990 WL 608693, at *3 (Cl. Ct. Spec. Mstr. 1990); *see also Vergara v. HHS*, 08-882V, 2014 WL 2795491, at *4 (Fed. Cl. Spec. Mstr. July 17, 2014) ("Special Masters frequently accord more weight to contemporaneously-recorded medical symptoms than those recorded in later medical histories, affidavits, or trial testimony.") *See also Cucuras v. HHS*, 993 F.2d 1525, 1528 (Fed. Cir. 1993) (noting that "the Supreme Court counsels that oral testimony in conflict with contemporaneous documentary evidence deserves little weight").)

Here, the pertinent medical records do *not* support Dr. Bellanti's assumptions about the supposed immediate reaction of N.B. to his vaccinations, in which, according to his parents, N.B. had a fever of 104° for two days, accompanied by loud screaming and uncontrollable crying. When N.B. was taken back to the doctor ten days after the vaccination, on June 23, 2001, the note of the visit does *not mention any part* of the alleged immediate reaction of June 13-15. (Ex. 45, p. 30.) In fact, the note states specifically that N.B.'s parent "denies illness symptoms," other than the rash, and that the parent reported an *absence* of fever in N.B. (*Id.*)[8] In my view, if N.B. had actually experienced the immediate reaction on June 13-15 later alleged by his parents, such reaction *would certainly have been reported* at the June 23 visit.

"To the extent that it relies on the testimony of the petitioners' witnesses as to the occurrence and timing of events, [expert medical opinion] must stand or fall with the fact testimony." (*Murphy v. HHS*, 90-882V, 1991 WL 74931, at *3 (Fed. Cl. Spec. Mstr. April 25, 1991) (*aff'd* 23 Cl.Ct. 726 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. denied*, 113 S. Ct. 463 (1992).) Thus, because I decline to credit Petitioners' testimony[9] with regard to N.B.'s alleged immediate reaction to his June 13 vaccinations, I likewise decline to accept Dr. Bellanti's opinion based upon on that testimony.

B. The record also contradicts Dr. Bellanti's assumption that N.B. experienced a sharp developmental regression following his vaccinations.

In addition to assuming a severe immediate vaccine reaction, Dr. Bellanti testified that his opinion was also based upon the assumption that N.B. experienced a *regression* of developmental skills after his vaccinations of June 13, 2001. For example, Dr. Bellanti testified that N.B. experienced a "significant deterioration" after his June 13 vaccinations (Tr. 56), and at another point answered "yes" to a question about whether N.B. experienced a "regression" after those vaccines (Tr. 85). In particular, Dr. Bellanti contended that Dr. Altman's progress note of

[8] At Ex. 45, p. 30, the symbol of a circle with horizontal line through it, prior to the word "fever," is commonly used in medical records; here, it means "no fever."

[9] I stress that I am not questioning the sincerity of Dr. and Mrs. Brook. I have no reason to doubt that they believe their recollections to be accurate. I simply find that their testimony does not have sufficient indicia of reliability to be trusted over the medical records, which constitute a conflicting, contemporaneously-recorded, recitation of the facts.

November 7, 2001, demonstrated a regression by reflecting a "change in attitude" by Dr. Altman regarding N.B.'s condition. (Tr. 85.) In that regard, Dr. Altman's record of that November 2001 visit indicates for the first time a diagnostic impression of "static encephalopathy with global delay," and includes a note that N.B. should be monitored for ASD. (Ex. 7, p. 18.) This, Dr. Bellanti argued, marks a contrast to Dr. Altman's notations immediately prior to N.B.'s vaccinations, wherein Dr. Altman indicated that N.B. was making "excellent gains." (Tr. 89.) Thus, Dr. Bellanti contended that "[N.B.] was progressing satisfactorily before the vaccine [sic] and then there was a deterioration or a *reversal* of that slow progression." (Tr. 86, emphasis added.)

Like the allegation of a severe immediate post-vaccine reaction, however, this second factual assumption of Dr. Bellanti is *not* borne out by a full examination of the record in this case.

Dr. McCusker, in contrast to Dr. Bellanti, argued that she did *not* interpret the medical records to show a *regression* in N.B.'s behavior after the June 13 vaccinations. She explained that there is an important distinction between a "failure to achieve" developmental milestones, and a "pathologic process that has arrested, stopped or regressed a child." (Tr. 115-17.) She opined that Dr. Altman's diagnosis of a "static" encephalopathy in November 2001 was the result of N.B.'s *ongoing* failure to *timely achieve milestones*, as opposed to resulting from a regression or deterioration as Dr. Bellanti argued. (Tr. 115-17, 133, 161-62.)

Asked about Dr. and Mrs. Brook's perception of post-vaccine changes in their son, Dr. McCusker explained that "as [a] child gets older, from the age of one to the age of two, there are many different developmental stages that the child goes through. And with each stage, there's a new challenge. If you have a child who is developmentally delayed, those challenges may become magnified. And it is still part of this child's developmental course, not because there's a dramatic change." (Tr. 145-46.) Dr. McCusker noted that N.B.'s medical records show that concerns regarding N.B.'s development began at around six to eight months of age, and that as he aged, N.B.'s developmental problems were noted "from the first indications that one can usually pick up a problem." (Tr. 106-07.) For example, Dr. McCusker explained that developmentally, milestones related to motor function are not expected to arise until between four to eight months, and skills related to independent play aren't expected until around 18 months. (Tr. 128, 144.) Dr. McCusker opined that as N.B. aged in the months just after the relevant vaccinations, he was expected to meet more milestones, but failed to do so. (*E.g.*, Tr. 132.) She opined that the fact that N.B. received vaccines on June 13, 2001, and was diagnosed in November 2001 with static encephalopathy, did *not* constitute good evidence that those vaccines *caused* any injury to N.B. (Tr. 160-62.)

Dr. Bellanti, by contrast, was not able to substantiate his assertion that N.B. experienced a *regression* soon after his vaccinations, as opposed to a continued failure to achieve milestones as Dr. McCusker argued. When asked to compare N.B.'s developmental course to the typical course of ASD, Dr. Bellanti indicated that he could not, because it was beyond his expertise. (Tr. 94.) Asked whether Dr. Altman used the word "regression" in his November 2001 note, Dr. Bellanti conceded that he had not. (Tr. 85-86.) Dr. Bellanti also acknowledged that he found no evidence of "regression" in N.B.'s physical therapy records for the months following N.B.'s June 13 vaccinations (*id.*), and that N.B.'s medical records show that he was already developmentally delayed at the time of his June 13 vaccinations (Tr. 73).

Nor, in fact, does Dr. Bellanti's assertion that N.B. experienced a post-vaccine *regression* even square with Dr. and Mrs. Brook's recollections. Dr. Brook testified that after the vaccinations, N.B. continued to make progress in physical therapy, albeit "very slowly." (Tr. 27.) Similarly, when asked about N.B.'s post-vaccination progress in physical therapy, Mrs. Brook testified that "he wasn't making the same kind of progress" and that "the work was hard." (Tr. 44-45.) She did not, however, indicate that N.B. regressed. This is consistent with the way in which she reported N.B.'s history to his speech therapist in August of 2002. That is, N.B.'s speech therapy records at 26 months of age indicate that "the mother reported all developmental milestones with [N.B.] have followed the normal progression; however, he has been very late." (Ex. 27, p. 25.)

And in any event, Dr. Altman's records for N.B.'s examinations of June 6 and November 7, 2001, the very records that Dr. Bellanti compared in arguing that a regression occurred in between the two visits, actually show, despite Dr. Altman's changing diagnostic impression, that N.B. had basically the *same developmental skills* at both visits—namely, that he had three to five words, and was sitting, crawling, and beginning to stand, but not yet walking. (*Compare* Ex. 7, p. 18, to Ex. 7, p. 19.) [10] In addition, Dr. Altman's subsequent record, made in March of 2002, indicates that N.B. was making "definitive but slow progress." (Ex. 7, p. 17.) In this regard, Dr. Bellanti seemed to be unable to point to any specific skills that N.B. allegedly *lost* during the period from June to November of 2001. (Tr. 88-94.) Further, while Dr. Bellanti generally contended that N.B. lost language skills after the vaccination, he also acknowledged that questions about N.B.'s language development had already been raised *prior to* the vaccinations. (Tr. 77.) Indeed, Dr. Altman had noted that N.B.'s language should be monitored as early as June 6, 2001, before he received the vaccinations at issue in this case. [11] (Ex. 7, p. 19.)

Thus, although N.B. undoubtedly continued to experience worsening symptoms of ASD after receiving his vaccinations of June 13, 2001, Dr. Bellanti's assertion of a developmental *regression* after those vaccinations is *not* supported by the record of this case. Dr. Bellanti never made a persuasive case that N.B.'s history between June 13 and November 7 was different from

[10] Although Dr. Altman noted that N.B. was "normal" in his June 6, 2001, record, he also recommended continued physical therapy and language monitoring. (Ex. 7, p. 19.) Dr. McCusker persuasively explained that the "normal" notation is misleading or semantic, in that it was a "snap shot" of N.B.'s progress with aggressive physical therapy into a broad developmental range of normal, but it was *not* an indication, as evidenced by Dr. Altman's prescriptions of continued therapies, that N.B. was destined to *remain* in that "normal" range as development progressed. (Tr. 133-37.) Moreover, Dr. Bellanti seemingly agreed, when he acknowledged that N.B. was "moderately, modestly" developmentally delayed *prior* to the June 13 vaccinations. (Tr. 73.)

[11] Although both Dr. Brook and Mrs. Brook testified that N.B. stopped speaking, or lost speech skills, after his vaccinations in question (Tr. 27-28, 43), they both acknowledged that prior to his vaccinations, N.B. had only just begun to babble, with "a few" words such as mama and dada (Tr. 27-28, 40). Significantly, Dr. Altman's record of November 7, 2001, indicates that at 17 months of age, approximately five months post-vaccinations, N.B. had 3-5 words and babbled. (Ex. 7, p. 18.) In March of 2002, at about 21 months of age, Dr. Altman noted "definite" language delays, but gave no indication of regression. (Ex. 7, p. 17.) And at 26 months of age, N.B.'s speech therapy records indicate that by that time he had approximately 10 words (in contrast to the 3-5 words pre-vaccinations.) (Ex. 27, p. 25.)

what one might expect of a child who had already exhibited early symptoms of ASD prior to June 13. Rather, it appears, as Dr. McCusker argued, that between June 13 and November 7 of 2001, N.B. was experiencing *ongoing* delays that began *prior* to his June 13 vaccinations; after those vaccinations he simply *continued* to miss milestones.

C. Summary

In sum, the most obvious reason to reject Dr. Bellanti's and Petitioners' causation claim in this case is that Dr. Bellanti based his causation theories on two *distinctly flawed* assumptions. First, he assumed the accuracy of the testimony of N.B.'s parents that N.B. experienced a *severe immediate reaction* to his vaccinations in question, consisting of two days of very high fever plus loud screaming and uncontrollable crying. However, based upon the medical records, I conclude that such alleged reaction never in fact happened.

Second, Dr. Bellanti also based his opinion on the assumption that N.B. suffered a "significant deterioration" and "regression" of skills during the five months after the vaccinations in question. However, for the reasons discussed above, I also conclude that this assumption was factually incorrect.

Therefore, because Dr. Bellanti, Petitioners' sole expert witness, based his causation opinion on two *clearly flawed* factual assumptions, I could end my analysis of this case at this point--Petitioners have clearly failed to prove their causation case via Dr. Bellanti's flawed testimony. However, in the interest of completeness, in the pages to follow I will explain several other reasons for rejecting Petitioners' causation claim in this case.

VIII

ADDITIONAL REASONS TO CREDIT DR. McCUSKER'S OPINION OVER THAT OF DR. BELLANTI

As noted above, because Dr. Bellanti based his testimony on clearly flawed factual assumptions, his causation opinion can be readily dismissed for that reason alone. But I will also briefly discuss certain additional reasons to discount Dr. Bellanti's opinion.

In general, I simply found the presentation of Dr. McCusker to be more logical and more persuasive. Despite acknowledging that N.B. has been diagnosed with ASD, Dr. Bellanti did not point to any *evidence* that would suggest that any of N.B.'s vaccinations of June 13, 2001, could have caused or aggravated his ASD. And although he discussed several mechanisms which might be "possible explanations" of N.B.'s condition, he appeared merely to be throwing out possibilities, and did not address those mechanisms convincingly. Moreover, Dr. McCusker effectively refuted his points in that regard.

A. Dr. Bellanti has pointed to no evidence indicating that the vaccines at issue could have caused or aggravated N.B.'s ASD.

First, I note that, regardless of the specific mechanism at work, Dr. Bellanti has clearly failed to offer any evidence that the vaccines at issue *could have* caused or aggravated N.B.'s neurologic disorder, which has been diagnosed as an ASD. Although Dr. Bellanti argued that N.B. experienced an encephalopathy that resulted in global developmental delay, he conceded

that N.B.'s symptoms "are consistent with autism spectrum disorder." (Ex. 43, p. 9.) He also specifically acknowledged in his expert report that N.B. was diagnosed as having an ASD. (Ex. 43, p. 10.) He admitted that he could not say whether N.B.'s course was different from the ordinary course of an ASD. (Tr. 94.) Further, while Dr. Bellanti linked N.B.'s ASD diagnosis to his vaccinations of June 13, 2001 (Tr. 56-57), at the hearing, when specifically asked if any of the autoimmune theories he cited in his opinion have been shown to lead to ASD, Dr. Bellanti responded "now, that's a subject that's highly controversial. *I don't think the data are in yet to support that*." (Tr. 101-02, emphasis added.)

Indeed, Dr. Bellanti's expert report cites no medical literature supporting his contention that any of the vaccinations in question[12] can, through autoimmune encephalopathy or otherwise, cause ASD or ASD-like symptoms. Rather, he stated in a conclusory manner, and wholly without support, that "[i]t should be obvious, however, that if a vaccine is capable of producing the severe encephalopathy described in the table[13], then that vaccine is also capable of producing a milder encephalopathy or one that affects the child in different ways. Depending on what areas of the brain are injured, the encephalopathy can result in autistic symptoms."[14] (Ex. 43, pp. 10-11.) Indeed, Dr. Bellanti not only failed to cite any supporting literature for this contention, he did not even describe what area of the brain he believed would need to be injured in order to produce ASD-like symptoms. [15]

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[12] I note that at most times, Dr. Bellanti referred simply to "the vaccines" that N.B. received on June 13, 2001, as likely causing or aggravating his condition, without distinguishing among the several vaccines received on that date. (*E.g.*, Ex. 43, pp. 10, 12; Tr. 56.) However, Dr. Bellanti's main theory was one of "viral persistence"--*i.e.*, that one of the "live" viral vaccines that N.B. received on June 13, 2001, *remained alive* in N.B.'s body. And he explained that the pneumococcal (Prevnar) vaccine that N.B. received on that day was a "killed virus" vaccine, while only the varicella and MMR vaccines contained live viruses. (Tr. 57.) So it was not clear whether Dr. Bellanti pointed only to the varicella and MMR viruses, and excluded the pneumococcal vaccine. This lack of clarity is another example of the loose nature of Dr. Bellanti's entire presentation in this case.

[13] Dr. Bellanti was presumably referring to the "Vaccine Injury Table" under which, in certain narrowly-defined circumstances, a particular type of "encephalopathy" can be presumed to be caused by an *MMR* vaccination. *See* § 300aa-14(a); 42 C.F.R. § 100.3. I note, however, that despite Dr. Bellanti's apparent reference to the listing of encephalopathy on the Vaccine Injury Table, Petitioners have argued their case exclusively on a "cause-in-fact" basis, and have *not* attempted to demonstrate that N.B.'s condition fits the narrow definition of encephalopathy included in the Vaccine Injury Table. (*See* ECF No. 52.)

[14] More specifically, at the hearing Dr. Bellanti argued that if it is possible for the MMR vaccination to cause "acute disseminated encephalomyelitis" ("ADEM"), then it must also be capable of causing other types of brain dysfunction. (Tr. 59.) Again, however, Dr. Bellanti did not substantiate this assertion with any literature related to either ADEM or ASDs. Moreover, Dr. McCusker disputed that she agreed that ADEM could be caused by the MMR vaccine. (Tr. 151.) Although she indicated in her expert report that reports exist indicating that some instances of ADEM were "temporally associated" with the MMR vaccine (Ex. A, p. 7), she argued that the presence of that association was insufficient to show "what causes" ADEM. (Tr. 151.)

[15] It is worth noting that Dr. McCusker agreed with the statement that "anything that injures the brain, if it injures the right parts of the brain, can result in symptoms of autism spectrum disorder." (Tr. 124.) Thus,

In his expert report and testimony, the only medical literature Dr. Bellanti cited that *allegedly* linked vaccination with autistic regression was in specific regard to patients with *mitochondrial disorders*. (Ex. 43, pp. 10-12, fns. 3, 4.) However, as will be described in Section IX below, Dr. Bellanti never opined, nor sought to demonstrate, that N.B. had any mitochondrial dysfunction.

Dr. Bellanti's admission that "the data are not in yet" to support his theory, and his failure to cite any medical literature on point, are particularly notable in light of Dr. McCusker's assertion that, despite having familiarity with the relevant medical literature, she "has yet to find" any medical literature supporting a link between vaccinations and autism. (Tr. 162-63.) Dr. McCusker was of the clear opinion that N.B. "followed the course of many, many children who have, unfortunately, autism spectrum disorder and developmental delays." (Tr. 122.) Dr. Bellanti, who admitted that he was unqualified to discuss whether N.B.'s developmental delay fit the pattern of an ASD (Tr. 94), effectively left Dr. McCusker's opinion on this point unchallenged.

Thus, even if I accepted Dr. Bellanti's theoretical description of autoimmune encephalopathy and its mechanisms at face value, I would still find Dr. Bellanti's causation opinion in this case to be unpersuasive, because he failed to substantiate his claim that such a process could ultimately result in the *ASD* with which N.B. has been diagnosed.

B. Dr. Bellanti seemed to be merely throwing out possibilities.

Turning to the question of what *mechanism* could have resulted in static encephalopathy in N.B.'s case, Dr. Bellanti's opinion appeared to lack both focus and conviction. To the extent that his expert opinion included a multitude of possibilities, it was seemingly tentative and clouded by doubt. Moreover, in several instances Dr. Bellanti appeared to effectively acknowledge that his opinion was speculative. Ultimately, his opinion seemed to expound upon what is *possible*, more so than shedding any light on what is *likely*.

For example, in his expert report, Dr. Bellanti asserted that "there are *a number of medical theories* that explain how the vaccines received by [N.B.] on June 13, 2001, *could* either cause a post-vaccinal encephalopathy or significantly aggravate an underlying condition resulting in a regressive encephalopathy with features of ASD." (Ex. 43, p. 11, emphasis added.) Dr. Bellanti not only listed four such theories, he also included a broad "catch-all," writing that N.B.'s condition might also be explained by "such other theories that I have discussed in other reports in this program." (*Id.*)

Among the theories specifically discussed in Dr. Bellanti's report are molecular mimicry, polyclonal activation, bystander effect, and adjuvant effect. (Ex. 43, p. 11.) At the hearing, however, Dr. Bellanti was asked which mechanism he thought was most likely to be at play in N.B.'s case. He contradicted his own expert report and discounted the possibility that molecular

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to the extent that Dr. McCusker acknowledged that a brain injury might be capable of resulting in ASD under the right circumstances, she seemingly agreed with Dr. Bellanti's statement that "depending on what areas of the brain are injured, the encephalopathy can result in autistic symptoms." (Ex. 43, pp. 10-11.) However, the fact remains that Dr. Bellanti has not substantiated his opinion either that the vaccines in question can operate *in general* to injure the brain in such a way as to cause ASD, or that any vaccine or vaccines did so *in N.B.'s case specifically*.

mimicry might be involved, stating that "it could be the bystander or polyclonal activation." (Tr. 98.)

Dr. Bellanti further testified that he could not narrow the mechanism down any further, indicating that his two possible mechanisms, "polyclonal activation" or "bystander effect," both involve "the theory of persistence of antigen" in N.B.'s body. (Tr. 99.) Dr. Bellanti indicated that he was presenting these two mechanisms as a "possible" explanation for N.B.'s condition (Tr. 99), and seemed to concede that there exists no "direct" evidence for his causation theory (*Id.*). Although Dr. Bellanti did at another point state that he was asserting his opinion of vaccine causation "within a reasonable certainty" (Tr. 56), he admitted that there were no clinical studies in N.B.'s case that would support his theory of antigen persistence (Tr. 64, 100).

At times, indeed, Dr. Bellanti's opinion seemed to be based on mere guesswork. That is, while describing his theory that N.B.'s encephalopathy was caused by antigen persistence and infiltration of the central nervous system, he testified that "there's no – there are no direct studies, of course, in [N.B.] that anybody isolated virus, but it's *tempting to offer that possibility*, particularly in a child who developed a high fever, inconsolable crying, something happened after that vaccine." (Tr. 64, emphasis added.) In fact, Dr. Bellanti explicitly characterized the basis of his opinion as *assumption*, stating that "You know, if you've got somebody with minimal damage who's starting to talk, who's starting to stand up, then suddenly he gets a set of vaccines and everything stops, you know, it doesn't take a rocket engineer to *assume* that there's a causal relationship."[16] (Tr. 83, emphasis added.) He also at another point referred to his theory as a "distinct possibility." (Tr. 68.) Further, although his primary causation theory was that a live virus from a vaccine "persisted" in N.B. and thereby caused a brain injury (encephalopathy), on cross-examination he admitted that he "can't say" that such persistence actually happened; it was merely a "possibility." (Tr. 100.)

Moreover, Dr. Bellanti would not even commit in his expert report to opining that N.B. in fact experienced a static encephalopathy, arguing instead that N.B. may alternatively have experienced an autistic regression related to mitochondrial dysfunction. (Ex. 43, pp. 11-12.) He wrote that "I should also point out that, if [N.B.'s] prior vaccines (and/or difficulty breathing at birth) did in fact result in mitochondrial dysfunction, then his autistic regression after the June 13, 2001 vaccinations could also be explained by something as simple as 'autistic regression caused by fever.'" (Ex. 43, p. 11.) Despite raising this possibility, however, as described in Section IX below, Dr. Bellanti made no attempt to demonstrate that N.B. actually suffered any mitochondrial dysfunction.

To be sure, Petitioners are *not* obligated to prove the specific biological *mechanism* of injury as part of their burden of proof. (*See, e.g., Knudsen v. HHS*, 35 F.3d 543, 549 (Fed. Cir. 1994).) Nonetheless, Dr. Bellanti's inability to point with confidence to any *likely* or *probable* theory of causation undermines Petitioners' case as a whole. In fact, the overall tentative nature of Dr. Bellanti's opinion was crystalized during the hearing when he conceded that N.B. had problems at birth that left him with developmental delays, before further stating that "it's a difficult thing to know whether it was all due to anoxia [at birth]." (Tr. 55-56.) In total, Dr.

[16] Of course, for the reasons previously discussed in Section VII, in addition to revealing speculative thinking, this statement of Dr. Bellanti was based on faulty factual predicates as well.

Bellanti seemed either unwilling or unable to identify even what he believes N.B.'s injury actually to be, let alone offering a solid opinion regarding its cause.

C. Dr. McCusker effectively refuted Dr. Bellanti's theories

In any event, even setting Dr. Bellanti's seeming uncertainty aside, those theories that Dr. Bellanti did posit were persuasively refuted by Dr. McCusker. Although Dr. McCusker agreed as a general matter that the "polyclonal activation" and "bystander effect" theories presented by Dr. Bellanti are "viable" explanations of how a vaccination or infection *might* trigger autoimmunity (Tr. 157), she presented a number of points which cast significant doubt on the question of whether either of these processes could have been at work *in N.B.'s case*. That is, in addition to disputing the factual assumptions upon which Dr. Bellanti relied (as discussed in Section VII above), Dr. McCusker also argued that N.B.'s clinical course was missing other key indicators that would have been present if Dr. Bellanti's theory was correct.

At base, Dr. Bellanti's opinion – regardless of the specific mechanism at work – is that N.B. was unable, through either his innate or adaptive immune systems, to completely eliminate the live viruses[17] contained in the vaccines that he received on June 13, 2001. This alleged persistence within N.B. of a live virus from a vaccine supposedly caused autoimmune damage (encephalopathy) to N.B.'s brain. (Tr. 61-64.) Dr. McCusker, however, opined that there is no evidence of viral persistence in this case. (Tr. 117.) If N.B. had been experiencing viral persistence following the failure of his innate and adaptive immune systems, she argued, then one would expect a "sick" child. (Tr. 117-20.) In particular, Dr. McCusker noted that Dr. Bellanti's "bystander effect" theory, because it is based on proximity between the antigen and the so-called "bystander" (Tr. 118), would mean that N.B. had "viremia," which would have included signs of illness such as days-long high fever (Tr. 119-20). N.B.'s medical records, however, as noted above, show no fever or other viremia symptoms.[18] Dr. McCusker also explained why Dr. Bellanti's "polyclonal activation" theory likewise is not viable in N.B.'s case. (Tr. 121-22.)

Significantly, Dr. McCusker also indicated that there is actually no evidence to support the idea that either of the two mechanisms suggested by Dr. Bellanti actually led to any kind of post-vaccination *progressive* encephalopathic process in N.B.[19] That is, she noted that N.B.'s history is lacking any indication of the type of significant non-developmental neurological impairment expected in the case of an encephalopathic process. (Tr. 115.) Specifically, Dr.

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[17] See footnote 13 above.

[18] To the extent that Petitioners allege that N.B. did have a high fever shortly after his MMR vaccination, Dr. McCusker's remarks make clear that a fever shortly after vaccination would be consistent with the immediate inflammatory response of the innate immune system and would be distinct from the type of fever she discussed as being associated with viremia. (Tr. 117-20.) In any event, for the reasons discussed in Section VII(A), I have declined to credit Petitioners' allegation that such a fever occurred.

[19] As previously indicated, Dr. McCusker agreed that a *static* encephalopathy is consistent with what N.B. experienced (Tr.115), but she emphasized that there is no reason to conclude that such static encephalopathy was caused or aggravated by his vaccines (*e.g.*, Tr. 122, 162.)

McCusker observed that significant inflammation of the central nervous system would be accompanied by symptoms such as fever, headache, drowsiness, vomiting, and irritability, which do not appear in N.B.'s medical records. (Tr. 142.)

Dr. McCusker also noted that studies of the MMR vaccination have shown no association between MMR vaccination and encephalopathy in children. (Ex. A, p. 7.)

Moreover, Dr. McCusker also pointed out that N.B.'s *MRI* was normal. (Tr. 114-15.) This is significant, Dr. McCusker noted, because autoimmune encephalopathies are associated with "distinctive lesions" that were not present on N.B.'s MRI. (Ex A, pp. 7-8.) The normal MRI also indicates a lack of inflammation in N.B.'s brain, although inflammation would be expected under Dr. Bellanti's theory. (Tr. 139.) Moreover, Dr. McCusker noted more generally in her expert report that "patients with profound autoimmune-mediated encephalopathy usually show changes on imaging studies." (Ex. A, p. 6.) Yet, despite identifying inflammation of the central nervous system as a possible result of the alleged persistence of the live virus from the vaccine within N.B., Dr. Bellanti likewise agreed not only that N.B.'s MRI was normal, but also that there was no clinical testing done to determine if N.B. had any ongoing presence of the measles virus. (Tr. 100-01.)

The apparent lack of symptoms of either viremia or encephalopathy noted by Dr. McCusker are important, because Dr. Bellanti acknowledged that there were no studies done in N.B.'s case which would have isolated the alleged viral persistence (Tr. 64), and also acknowledged that his opinion is based entirely on N.B.'s clinical presentation (Tr. 82-83). In short, Dr. Bellanti had no persuasive answer to any of Dr. McCusker's points. Again, as with the flawed factual assumptions discussed in detail in Section VII above, this leaves Dr. Bellanti's causation opinion without sufficient tether to the facts of this case, and far less persuasive than Dr. McCusker's presentation.

IX

PETITIONERS' ALTERNATIVE "MITOCHONDRIAL DYSFUNCTION" THEORY

In addition to Dr. Bellanti's primary theory discussed above, that N.B.'s vaccinations of June 13, 2001, caused an autoimmune reaction leading to encephalopathy, Petitioners have also briefly suggested an alternative theory about how vaccines might have caused or aggravated N.B.'s neurological disorder. I found no merit in this unsupported suggestion.

Petitioners suggested that N.B.'s condition might be the result of a "mitochondrial dysfunction" caused by "mercury toxicity," brought about by certain vaccines containing a preservative known as "thimerosal," which vaccines N.B. received on various dates prior to December 2000. (ECF No. 52, p. 25.) Although Petitioners raised this theory in their post-hearing brief, it not even clear that Dr. Bellanti was relying on it. He stated in his expert report that he is of the opinion that the causal role of the vaccinations of June 13, 2001, was clear "whether or not these [other] vaccines caused mitochondrial dysfunction." (Ex. 43, p. 10.) Moreover, he did *not* volunteer mitochondrial dysfunction as part of his opinion during the hearing in this case; it was raised only on cross-examination by respondent's counsel. (Tr. 96-97.) Nonetheless, in the interest of completeness, I note that, like Dr. Bellanti's principal theory, this alternative theory is similarly predicated on a faulty factual assumption. That is, Dr. Bellanti

has not established, nor even attempted to establish, that N.B. actually had a mitochondrial dysfunction.

Although Dr. Bellanti posited in his expert report that "[t]he porphyrins test results are suggestive of a role for mercury toxicity that may have contributed to his condition," and that "mercury has been demonstrated to cause mitochondrial dysfunction," he never opined that N.B. *actually had* a mitochondrial dysfunction. (Ex. 43, pp. 10-12.) Nor did he point to any diagnostic sign or symptom of mitochondrial dysfunction in N.B.'s history. When asked on cross-examination about mitochondrial dysfunction, Dr. Bellanti testified that N.B. had never been diagnosed as having any mitochondrial dysfunction, and that the only evidence in the clinical history of such dysfunction was "inferential." (Tr. 96-97). That is, Dr. Bellanti indicated that there was a reference to a single reading of elevated lactic acid in N.B.'s history. (Tr. 97-98.) He acknowledged, however, that a single such test was insufficient for a diagnosis. (*Id.*) Thus, even Dr. Bellanti acknowledged that there is no evidence to support this alternative theory in this case, since there is no evidence in the record of mitochondrial dysfunction.[20]

Therefore, I find no merit to Petitioners' alternative "mitochondrial dysfunction" theory.

X

PETITIONERS HAVE FAILED THE *ALTHEN* TEST

As noted above, in its ruling in *Althen,* the U.S. Court of Appeals for the Federal Circuit discussed the "causation-in-fact" issue in Vaccine Act cases. The court stated as follows:

> Concisely stated, Althen's burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between the vaccination and injury. If Althen satisfies this burden, she is "entitled to recover unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine."

Althen, 418 F.3d 1274, 1278 (Fed. Cir. 2005) (citations omitted). In the pages above, of course, I have already set forth in detail my analysis in rejecting Petitioners' "causation-in-fact" theory in this case. In this part of my Decision, then, I will briefly explain how that analysis fits specifically within the three parts of the *Althen* test, enumerated in the first sentence of the *Althen* excerpt set forth above. The short answer is that I find that Petitioners' theory in this case clearly does not satisfy the *Althen* test.

[20] Dr. McCusker, likewise, indicated that a single instance of elevated lactic acid is insufficient for the diagnosis of a mitochondrial dysfunction. (Tr. 158-59.) She also stressed that the scientific evidence linking mitochondrial disease and ASD is "very soft." (*Id.*) However, because Dr. Bellanti has not even sought to establish that N.B. had any mitochondrial dysfunction, I do not reach the question of whether such a link exists.

A. Relationship between Althen Prongs 1 and 2

One interpretive issue with the *Althen* test concerns the relationship between the first two elements of that test. The first two prongs of the *Althen* test, as noted above, are that the petitioners must provide "(1) a medical theory causally connecting the vaccination and the injury; [and] (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Initially, it is not absolutely clear how the two prongs differ from each other. That is, on their faces, each of the two prongs seems to require a demonstration of a "causal" connection between "the vaccination" and "the injury." However, a number of Program opinions have concluded that these first two elements reflect the analytical distinction that has been described as the "can cause" vs. "did cause" distinction. That is, in many Program opinions issued prior to *Althen* involving "causation-in-fact" issues, special masters or judges stated that a petitioner must demonstrate (1) that the *type* of vaccination in question *can* cause the *type* of injury in question, and also (2) that the *particular* vaccination received by the specific vaccinee *did* cause the vaccinee's *own* injury. *See, e.g., Kuperus v. HHS*, 2003 WL 22912885, at *8 (Fed. Cl. Spec. Mstr. Oct. 23, 2003); *Helms v. HHS*, 2002 WL 31441212, at *18 n. 42 (Fed. Cl. Spec. Mstr. Aug. 8, 2002). Thus, a number of judges and special masters of this court have concluded that Prong 1 of *Althen* is the "can cause" requirement, and Prong 2 of *Althen* is the "did cause" requirement. *See, e.g., Doe 11 v. HHS*, 83 Fed. Cl. 157, 172-73 (2008); *Nussman v. HHS*, 83 Fed. Cl. 111, 117 (2008); *Banks v. HHS*, 2007 WL 2296047, at *24 (Fed. Cl. Spec. Mstr. July 20, 2007); *Zeller v. HHS*, 2008 WL 3845155, at *25 (Fed. Cl. Spec. Mstr. July 30, 2008). And, most importantly, the *Federal Circuit* confirmed that interpretation in *Pafford*, ruling explicitly that the "can it?/did it?" test, used by the special master in that case, was equivalent to the first two prongs of the *Althen* test. *Pafford v. HHS*, 451 F.3d at 1352, 1355-56 (Fed. Cir. 2006). Thus, interpreting the first two prongs of *Althen* as specified in *Pafford*, under Prong 1 of *Althen* a petitioner must demonstrate that the *type* of vaccination in question can cause the *type* of condition in question; and under Prong 2 of *Althen* that petitioner must then demonstrate that the *particular* vaccination did cause the *particular* condition of the vaccinee in question.

Moreover, there can be no doubt whatsoever that the *Althen* test ultimately requires that, as an overall matter, a petitioner must demonstrate that it is "more probable than not" that the particular vaccine was a substantial contributing factor in causing the particular injury in question. That is clear from the statute itself, which states that the elements of a petitioner's case must be established by a "preponderance of the evidence." § 300aa-13(a)(1)(A). And, whatever is the precise meaning of Prongs 1 and 2 of *Althen*, in this case the overall evidence falls far short of demonstrating that it is "more probable than not" that any of the vaccines that N.B. received contributed to the causation or aggravation of N.B.'s tragic neurodevelopmental disorder.

B. Petitioners have failed to establish Prong 1 of Althen in this case

As explained above, under Prong 1 of *Althen* a petitioner must provide a medical theory demonstrating that the *type* of vaccine in question can cause the *type* of condition in question. Petitioners' primary theory is that N.B.'s vaccinations of June 13, 2001, resulted in an autoimmune encephalopathic process that resulted in symptoms consistent with ASD. However, as described above in Section VIII(A), Dr. Bellanti has *not* demonstrated that the types of vaccines received by N.B. can cause an autoimmune encephalopathy, nor has he shown that an

autoimmune encephalopathic process could result in ASD-like symptoms. Thus, Petitioners' claim clearly fails under *Althen* Prong 1.

C. Petitioners have failed to establish Prong 2 of Althen in this case

Under Prong 2, the Petitioners need to show that it is "more probable than not" that one or more of N.B.'s vaccinations *did* cause N.B.'s *own* condition. But this they have failed to do, for all of the reasons detailed above. Dr. Bellanti acknowledged that no test results were available to substantiate his opinion that N.B.'s vaccinations either caused or aggravated a static encephalopathy. Rather, he opined that a "cause and effect" relationship was demonstrated by N.B.'s alleged immediate severe vaccine reaction and his alleged post-vaccination regression. As described in Section VII, however, neither of these factual assumptions is supported by the record of this case. In addition, as described in Section VIII(C), Dr. McCusker persuasively refuted Dr. Bellanti's arguments concerning N.B.'s case. Thus, Petitioners have failed to establish Prong 2 of *Althen* in this case.[21]

D. Petitioners have failed to establish Prong 3 of Althen in this case

Since I have explained why Petitioners have failed to satisfy the *first* and *second* prongs of *Althen*, I need not discuss why Petitioners' case also fails to satisfy the *third* prong. However, I will note again that Dr. Bellanti's assumption of a "cause and effect" relationship based on the supposed presence of an immediate severe reaction and a post-vaccination regression is not supported by the record of this case. This would preclude any finding of a proximate temporal relationship between the vaccination and the injury, as required under *Althen* Prong 3.[22]

E. This is not a close case

As noted above, in *Althen* the Federal Circuit indicated that the Vaccine Act involves a "system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." 418 F.3d at 1280. Accordingly, I note here that this case ultimately is *not* a close case. For all the reasons set forth above, I found that Dr. Bellanti's theory was *not at all* persuasive, while Respondent's expert was *far* more persuasive.

XI

PETITIONERS' ARGUMENT CONCERNING "ALTERNATIVE CAUSE"

In their initial post-hearing brief, Petitioners argue that "[n]o other or alternate cause of N.B.'s injuries have been found," implying that this suggests that *vaccines* caused N.B.'s condition. (ECF No. 52, p. 24.) This argument, however, adds no support to their claim for an award.

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[21] To clarify, Petitioners have failed to show that N.B.'s autism was either *initially caused* by his vaccinations, or was *aggravated* in any way by his vaccinations.

[22] As noted in Section IX of this Decision above, Petitioners have also suggested an alternative theory of causation. For the reasons set forth in Section IX, this alternative theory also fails the *Althen* test.

In this regard, Dr. McCusker did point out that N.B. had a very complicated birth, and that the type of hypoxia he experienced at that time is often followed by developmental delay. (Tr. 105-06). Specifically, Dr. McCusker noted in her expert report that "[t]here is no evidence implicating the MMR vaccination in the onset or progression of encephalopathy in children. In contrast there is a clear association [between] perinatal asphyxia and hyperoxemia in the first hour of life and moderate to severe encephalopathy." (Ex. A, p. 7; *see* also Tr. 123.) At the hearing, Dr. McCusker further indicated that "we know that in moderate to severe cases, developmental delays *usually* follow perinatal hypoxia or perinatal asphyxia." (Tr. 106, emphasis added.) Although Dr. McCusker acknowledged that it's not possible to know how long N.B. was without oxygen, she stressed that the pH of his cord blood and his first "APGAR score" after birth indicate that his anoxia was likely more severe than mild. (Tr. 137-38.)

It is appropriate to consider Dr. McCusker's explanation regarding this other possible cause of N.B.'s condition *as part of evaluating Petitioners' "case-in-chief*." (*See, e.g. deBazan v. HHS*, 539 F.3d 1347, 1353-54 (Fed. Cir. 2008).) It is particularly appropriate in the context of this case, in which Petitioner's own expert, Dr. Bellanti, agreed that N.B.'s perinatal asphyxia could possibly explain N.B.'s condition. In his expert report, Dr. Bellanti indicated that among the factors potentially bearing on any explanation of N.B.'s condition is "the possibility that he had a mild encephalopathy (brain injury) from the anoxia at birth." (Ex. 43, p. 12.) At the hearing, Dr. Bellanti went a step further, and in fact conceded that "it's a difficult thing to know whether it was all due to anoxia [at birth]." (Tr. 55-56.) This concession by Dr. Bellanti not only adds weight to Dr. McCusker's opinion that N.B.'s condition may have been the result of perinatal hypoxia or perinatal asphyxia, but also, again, underscores the uncertainty of Dr. Bellanti's own opinion.

However, I must stress that in this case, the Petitioners *never carried their burden* of establishing a *prima facie* case that any vaccinations likely had any role in causing or aggravating N.B.'s neurological disorder. Therefore, the burden *never shifted* to Respondent to demonstrate that N.B.'s disorder was "due to factors unrelated to the vaccination." § 300aa-13(a)(1)(B). (*de Bazan*, 539 F.3d at 1354.) I do *not* conclude in this case that N.B.'s birth trauma caused his disorder. I merely conclude that there has been no showing that it is probable that any *vaccinations*[23] had anything to do with causing or aggravating that disorder.[24]

XII

CONCLUSION

The record of this case demonstrates plainly that N.B. and his family have been through a tragic ordeal. I had the opportunity, in the courtroom during the evidentiary hearing, to listen to

[23] As Dr. McCusker testified, the causation of ASD is *not* well-understood by medical science at this time, so that it is quite common that a particular cause for an individual's ASD is never identified. (Tr. 123-24.)

[24] Petitioners' reply brief argues that the Petitioners' causation theory need not be proved to a "scientific certainty." That is certainly true. I require proof only to the level of a "preponderance of the evidence"--*i.e.*, more likely than not. (See fn. 7 above.) But Petitioners have fallen far, far short of that "more probable than not" standard.

the testimony of N.B.'s parents. I have also studied the records describing N.B.'s medical history, and the efforts of his family in caring for him. Based upon those experiences, the great dedication of N.B.'s family to his welfare is readily apparent to me.

Nor do I doubt that N.B.'s parents are sincere in their belief that N.B.'s vaccinations played a role in causing or aggravating N.B.'s neurological disorder. N.B.'s parents have heard the opinion of Dr. Bellanti, and perhaps other physicians, who profess to believe in a causal connection between vaccines and autism. After studying the extensive evidence in this case, I am convinced that the opinion provided by Petitioners' expert in this case, advising the Brook family that there is a causal connection between vaccinations and autism, was *quite wrong*. Nevertheless, I can understand why N.B.'s parents found such opinion to be believable under the circumstances. I conclude that the Petitioners filed this petition in good faith.

Thus, I feel deep sympathy for the Brook family. Further, I find it unfortunate that my ruling in this case means the Program will not be able to provide funds to assist this family, in caring for their child who suffers from a serious disorder. It is my view that our society does not provide enough assistance to families of *all* autistic children, regardless of the cause of their disorders. And it is certainly my hope that our society will find ways to ensure that in the future *much* more generous assistance is available to all such children. Such families must cope every day with tremendous challenges in caring for their autistic children, and all are deserving of sympathy and admiration. However, I must decide this case not on sentiment, but by analyzing the evidence. Congress designed the Program to compensate only the families of individual whose injuries or deaths can be linked causally, either by a Table Injury presumption or by a preponderance of "causation-in-fact" evidence, to a listed vaccine. In this case, the evidence advanced by Petitioners has fallen far short of demonstrating such a link. Accordingly, I conclude that the Petitioners in this case are *not* entitled to a Program award on N.B.'s behalf.[25]

IT IS SO ORDERED.

/s/ George L. Hastings, Jr.
George L. Hastings, Jr.
Special Master

[25] In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.